

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2040070	(X3) Date Survey Completed 02/22/2024
Name of Provider or Supplier Camelia Foundation, The	Street Address, City, State 3030 Covington Pike Ste 100, Memphis, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's testing personnel competency assessment policy, testing personnel competency assessment records and staff interview, the laboratory failed to follow its' own policy for performing annual competency assessment for one of four established testing personnel reviewed. The findings include: 1. Review of the laboratory policy for testing personnel competency assessment revealed that competency would "be performed and documented by the technical consultant initially, at 6 months, and annually thereafter." 2. Review of testing personnel competency assessment records revealed that annual competency was not performed for testing person six in 2023 (one of four established testing personnel reviewed). 3. During interview on 02/22/24 at 2:30 pm, the laboratory liaison and lead testing person confirmed the survey findings.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the laboratory procedure manual, quality assessment documentation and staff interview, the laboratory failed to follow its' own policy for quality assessment when it did not perform quarterly quality assessments in 2023 and did not perform patient test management activities when the quality assessment visits were performed in 2022, 2023 and 2024. The findings include: 1. Review of the laboratory's quality assessment policy revealed the following statements: "The technical consultant will perform and document the quality assessment at each visit." "This laboratory will have visits made quarterly." "The following reviews will be performed." Reviews included quality control, preventive maintenance, procedure manual, personnel, data log, patient test management, quality assessment. PATIENT TEST MANAGEMENT "This process is a random review of a varied number of patient charts to check for proper ID by 2 identifiers, potential adverse affect on the patient, successful QC, pm and correct and timely entrance into the chart or EMR. This process is a critical step in monitoring the quality assessment of the laboratory." 2. Review of quality assessment documentation revealed the following: Quarterly quarterly assessment was not performed for the 2nd quarter of 2023. Chart reviews as required in the plan were not documented for the quarterly assessments performed 10/22/22, 03/01/23, 09/22/23, 12/30/23, and 02/17/24. 3. The laboratory liaison confirmed the survey findings during interview on 02/22/24 at 2:30 pm.